CLAIMS

1. A method of treating fatigue, comprising, administering a therapeutic amount of a recombinant erythropoietin

2. The method of claim 1 wherein the recombinant Erythropoietin is selected from the group consisting of: Epoetin Omega, an Erythropoietin produced in baby hamster kidney cells, an Erythropoietin expressed from an Apa I restriction fragment of human genomic Erythropoietin DNA, an Erythropoietin having a glycosylation pattern characterized by the presence of N-linked glycosylated residues on at least three asparagine residues, an erythropoietin having an O-linked oligosaccharide content of less than 1 mole per mole of glycoprotein, an erythropoetin having one or more isoforms at pI 4.3, or 4.5, or 4.6, and a recombinant erythropoietin that retains substantially all of its *in vitro* biological activity after being subject to N-deglycosylation.

3. The method of claim 1 wherein the recombinant erythropoietin is Epoetin Omega.

4. The method of claim 1 wherein the fatigue is associated with a cancer.

5. The method of claim 1 wherein the fatigue is associated with liver dysfunction.

6. The method of claim 1 wherein the fatigue is associated with a hepatitis infection.

7. The method of claim 1 wherein the fatigue is associated with a heart condition.

8. The method of claim 1 wherein the fatigue is associated with an autoimmune disease.

9. The method of claim 8 wherein the autoimmune disease is arthritis.

10. The method of claim 1 wherein the fatigue is associated with chronic fatigue syndrome.

11. The method of claim 1 wherein the fatigue is associated with a cancer therapy.

12. The method of claim 11 wherein the cancer therapy is a chemotherapy.

13. The method claim 12 wherein the chemotherapy is a cisplatinum therapy.

14. The method of claim 11 wherein the erythropoietin is administered before, during or after the cancer therapy.

15. The method of claim 11 wherein the cancer therapy is radiation therapy.

16. A method of treating body or other pain comprising, administering a therapeutic amount of a recombinant erythropoietin

17. The method of claim 16 wherein the recombinant erythropoietin is selected from the group consisting of: Epoetin Omega, an erythropoietin produced in baby hamster kidney cells, an erythropoietin expressed from an Apa I restriction fragment of human genomic erythropoietin DNA, an erythropoietin having a glycosylation pattern characterized by the presence of N-linked glycosylated residues on at least three asparagine residues, an erythropoietin having an O-linked oligosaccharide content of less than 1 mole per mole of glycoprotein, an erythropoetin having one or more isoforms at pI 4.3, or 4.5, or 4.6, and a recombinant erythropoietin that retains substantially all of its *in vitro* biological activity after being subject to N-deglycosylation.

18. The method of claim 16 wherein the recombinant erythropoietin is Epoetin Omega.

19. The method of claim 16 wherein the vascular pain is associated with a cancer.

20. The method of claim 16 wherein the vascular pain is associated with liver dysfunction.

21. The method of claim 16 wherein the vascular pain is associated with a hepatitis infection.

22. The method of claim 16 wherein the vascular pain is associated with a heart condition.

23. The method of claim 16 wherein the vascular pain is associated with an autoimmune disease.

24. The method of claim 23 wherein the autoimmune disease is arthritis.

25. The method of claim 16 wherein the vascular pain is associated with a cancer therapy.

26. The method of claim 25 wherein cancer therapy is a chemotherapy.

27. The method claim 26 wherein the chemotherapy is a cisplatinum therapy.

28. The method of claim 25 wherein the erythropoietin is administered before, during or after the cancer therapy.

29. The method of claim 25 wherein the cancer therapy is a radiation therapy.

30. A method of treating a symptom in a subject comprising, administering at a frequency of once per week or less, a therapeutic amount of a recombinant erythropoietin selected from the group consisting of: Epoetin Omega, an erythropoietin produced in baby hamster kidney cells, an erythropoietin expressed from an Apa I restriction fragment of human genomic erythropoietin DNA, an erythropoietin having a glycosylation pattern characterized by the presence of N-linked glycosylated residues on at least three asparagine residues, an erythropoietin having an O-linked oligosaccharide content of less than 1 mole per mole of glycoprotein, an erythropoetin having one or more isoforms at pI 4.3, or 4.5, or 4.6, and a recombinant erythropoietin that retains substantially all of its *in vitro* biological activity after being subject to N-deglycosylation.

31. The method of claim 30 wherein the recombinant erythropoietin is Epoetin Omega.

32. The method of claim 30 wherein therapeutic amount is about 55-150 IU/kg.

33. The method of claim 30 wherein the therapeutic amount of recombinant erythropoietin does not elicit anti-erythropoietin IgG antibodies over a treatment period of 4-16 weeks.

34. The method of claim 30 wherein the symptom is selected from the group consisting of anemia, fatigue, dementia, and vascular pain.

35. The method of claim 30 wherein the symptom is anemia.

36. The method of claim 30 wherein the symptom is fatigue.

37. The method of claim 30 wherein the symptom is dementia.

38. The method of claim 30 wherein the symptom is vascular pain.

39. A method of treating a symptom in a subject having a condition adversely effected by a side effect of treatment with erythropoietin comprising, administering a therapeutic amount of a recombinant erythropoietin selected from the group consisting of: Epoetin Omega, an erythropoietin produced in baby hamster kidney cells, an erythropoietin expressed from an Apa I restriction fragment of human genomic erythropoietin DNA, an erythropoietin having a glycosylation pattern characterized by the presence of N-linked glycosylated residues on at least three asparagine residues, an erythropoietin having an O-linked oligosaccharide content of less than 1 mole per mole of glycoprotein, an erythropoetin having one or more isoforms at pI 4.3, or 4.5, or 4.6, and a recombinant erythropoietin that retains substantially all of its *in vitro* biological activity after being subject to N-deglycosylation; wherein the therapeutic amount is selected to provide a therapeutic benefit within a treatment

period without producing or exacerbating an adverse effect associated with treatment by a therapeutic amount of Epoetin Alfa or Beta.

40. The method of claim 39 wherein the recombinant erythropoietin is Epoetin Omega.

41. The method of claim 39 wherein the symptom is selected from the group consisting of anemia, fatigue, , and vascular pain.

42. The method of claim 39 wherein the symptom is anemia.

43. The method of claim 39 wherein the symptom is fatigue.

44. The method of claim 39 wherein the symptom is dementia.

45. The method of claim 39 wherein the symptom is vascular pain.

46. The method of claim 39 wherein the adverse side effect is increased blood pressure or hypertension.

47. The method of claim 39 wherein the adverse side effect is thrombosis.

48. The method of claim 39 wherein the adverse effect is increased platelet count.

49. The method of claim 39 wherein the condition is selected from the group consisting of hypertension, thrombosis, a heart condition, cancer, an autoimmune disease, liver dysfunction, hepatitis and treatment by chemotherapy or radiation therapy.

50. The method of claim 39 wherein the condition is a heart condition.

51. The method of claim 39 wherein the condition is an autoimmune disease.

52. The method of claim 51 wherein the autoimmune disease is rheumatoid arthritis.

53. The method of claim 39 wherein the condition is liver dysfunction.

54. The method of claim 39 wherein the condition is hepatitis.

55. The method of claim 39 wherein the condition is cancer.

56. The method of claim 39 wherein the therapeutic benefit is selected from the group consisting of increased RBC, increased HCT, increased hemoglobin, increased vigor, increased mental acuity or decreased pain.

57. The method of claim 39 wherein the recombinant erythropoietin is administered at a dose of 5-150 IU/Kg, one to three times per week.

58. The method of claim 39 wherein the recombinant erythropoietin is administered at a dose of 75-200 IU/Kg, once per week.

59. The method of claim 39 wherein the therapeutic benefit is obtained in about 1 to 5 weeks.

60. The method of claim 59 wherein the therapeutic benefit is maintained over a prolonged maintenance period without producing or exacerbating said adverse effect.

61. The method of claim 39 wherein the symptom is associated with a cancer therapy.

62. The method of claim 61 wherein the cancer therapy is a chemotherapy.

63. The method claim 62 wherein the chemotherapy is a cisplatinum therapy.

64. The method of claim 61 wherein the erythropoietin is administered before, during or after the cancer therapy.

65. The method of claim 61 wherein the cancer therapy is a radiation therapy.

66. A method of treating or preventing an anemic condition in a subject, comprising, administering a therapeutic amount of an erythropoietin selected from the group consisting of: Epoetin Omega, an erythropoietin produced in baby hamster kidney cells, an erythropoietin expressed from an Apa I restriction fragment of human genomic erythropoietin DNA, an

erythropoietin having a glycosylation pattern characterized by the presence of N-linked glycosylated residues on at least three asparagine residues, an erythropoietin having an O-linked oligosaccharide content of less than 1 mole per mole of glycoprotein, an erythropoetin having one or more isoforms at pI 4.3, or 4.5, or 4.6, and a recombinant erythropoietin that retains substantially all of its *in vitro* biological activity after being subject to N-deglycosylation; wherein the amount of recombinant erythropoietin is selected to provide a therapeutic benefit within a treatment period, and wherein said subject is non-responsive or adversely effected by treatment with a therapeutic amount of Epoetin Alfa or Beta.

67. The method of claim 66 wherein the erythropoietin is Epoetin Omega.

68. The method of claim 66 wherein the anemic condition is selected from the group consisting of renal anemia, anemia of malignant disease, anemia associated with chemotherapy, anemia of chronic disease, anemia in AIDS, anemia of prematurity, anemia of thalasemia, anemia of autoimmune hemolytic disease, and aplastic anemia.

69. The method of claim 66 wherein the treatment is for preventing an anemic condition associated with an operative procedure.

70. The method of claim 66 wherein the recombinant erythropoietin is administered in a preoperative step.

71. The method of claim 66 wherein the operative procedure is bone marrow transplantation.

72. The method of claim 66 wherein the anemic condition is associated with a heart condition.

73. The method of claim 66 wherein the anemic condition is associated with liver dysfunction.

74. The method of claim 66 wherein the anemic condition is associated with hepatitis.

75. The method of claim 66 wherein the anemic condition is associated with cancer.

76. The method of claim 66 wherein the therapeutic benefit is selected from the group consisting of increased RBC, increased HCT, increased hemoglobin, and increased vigor.

77. The method of claim 66 wherein the recombinant erythropoietin is administered at a dose of about 5 to about 150 IU/Kg, one to three times per week.

78. The method of claim 66 wherein the recombinant erythropoietin is administered at a dose of about 10 to about 100 IU/Kg, one to two times per week.

79. The method of claim 66 wherein the recombinant erythropoietin is administered at a dose of about 10 to about 75 IU/Kg, one to two times per week.

80. The method of claim 66 wherein the recombinant erythropoietin is administered at a dose of about 25 to about 60 IU/Kg, two times per week.

81. The method of claim 66 wherein the recombinant erythropoietin is administered at a dose of about 25 to about 35 IU/Kg, two times per week.

82. The method of claim 66 wherein the recombinant erythropoietin is administered at a dose of about 75 to about 150 IU/Kg, once per week.

83. The method of claim 66 wherein the recombinant erythropoietin is administered at a dose of about 75 to about 100 IU/Kg, once per week.

84. The method of claim 66 wherein the treatment period includes a titration period and the recombinant erythropoietin is administered at an initial dose of about 50 to about 100 IU/kg per week during the titration period and is adjusted by about 5 to about 25 IU/Kg/week to obtain a hemoglobin count of about 10 to about 12 g/dl.

85. The method of claim 66 wherein the treatment period further includes a maintenance period, and the recombinant erythropoietin is administered at a dose of about 40-60 IU/kg per week during the maintenance period.

86. The method of claim 66 wherein the anemic condition is associated with a cancer therapy.

87. The method of claim 86 wherein the cancer therapy is a chemotherapy.

88. The method of claim 97 wherein the chemotherapy is a cisplatinum therapy.

89. The method of claim 86 wherein the recombinant erythropoietin is administered before, during, or after the cancer therapy.

90. A formulation or kit comprising a therapeutic amount of Epoetin Omega formulated for the treatment method according to claim 66.

91. The formulation or kit of claim 98 further including instructions for administering the therapeutic amount of recombinant erythropoietin to achieve the therapeutic benefit.

92. The formulation or kit according to claim 99 wherein the instructions include reference to an amount of recombinant erythropoietin to be used in comparison to an amount of Epoetin Alfa or Beta used in other treatments.

93. A method of treating or preventing an anemic condition in a subject, comprising, administering a therapeutic amount of a recombinant erythropoietin selected from the group consisting of: Epoetin Omega, an erythropoietin produced in baby hamster kidney cells, an erythropoietin expressed from an Apa I restriction fragment of human genomic erythropoietin DNA, an erythropoietin having a glycosylation pattern characterized by the presence of N-linked glycosylated residues on at least three asparagine residues, an erythropoietin having an O-linked oligosaccharide content of less than 1 mole per mole of glycoprotein, an erythropoetin having one or more isoforms at pI 4.3, or 4.5, or 4.6, and a recombinant erythropoietin that retains substantially all of its *in vitro* biological activity after being subject to N-deglycosylation; wherein the therapeutic amount is selected to provide a therapeutic benefit within a treatment period without producing or exacerbating an adverse effect selected from the group consisting of increased blood pressure or hypertension.

94. The method of claim 93 wherein the recombinant erythropoietin is Epoetin Omega.

95. The method of claim 93 wherein the anemic condition is selected from the group consisting of renal anemia, anemia of malignant disease, anemia associated with chemotherapy, anemia of chronic disease, anemia in AIDS, anemia of prematurity, anemia of thalasemia, anemia of autoimmune hemolytic disease, and aplastic anemia.

96. The method of claim 93 for treating or preventing an anemic condition associated with an operative procedure.

97. The method of claim 93 wherein the recombinant erythropoietin is administered in a preoperative step.

98. The method of claim 93 wherein the operative procedure is bone marrow transplantation.

99. The method of claim 93 wherein the blood pressure includes a diastolic or systolic measurement that is not increased by more than 10 mm Hg during the treatment period.

100. The method of claim 93 wherein the blood pressure includes a diastolic or systolic measurement that is not increased by more than 1 mm Hg per unit rise in hemoglobin count (g/dl).

101. The method of claim 93 wherein a risk of developing hypertension in a population of subjects treated with the recombinant erythropoietin is less than 15% over a population of subjects treated with a placebo.

102. The method of claim 93 wherein the anemic condition is associated with a heart condition.

103. The method of claim 93 wherein the anemic condition is associated with liver dysfunction.

104. The method of claim 93 wherein the anemic condition is associated with hepatitis.

105. The method of claim 101 wherein the anemic condition is associated with cancer.

106. The method of claim 93 wherein the therapeutic benefit is selected from the group consisting of increased RBC, increased HCT, increased hemoglobin, and increased vigor.

107. The method of claim 93 wherein the recombinant erythropoietin is administered at a dose of about 5 to about 150 IU/Kg, one to three times per week.

108. The method of claim 93 wherein the recombinant erythropoietin is administered at a dose of about 10 to about 100 IU/Kg, one to two times per week.

109. The method of claim 93 wherein the recombinant erythropoietin is administered at a dose of about 10 to about 75 IU/Kg, one to two times per week.

110. The method of claim 93 wherein the recombinant erythropoietin is administered at a dose of about 25 to about 60 IU/Kg, two times per week.

111. The method of claim 93 wherein the recombinant erythropoietin is administered at a dose of about 25 to about 35 IU/Kg, two times per week.

112. The method of claim 93 wherein the recombinant erythropoietin is administered at a dose of about 75 to about 150 IU/Kg, once per week.

113. The method of claim 93 wherein the recombinant erythropoietin is administered at a dose of about 75 to about 100 IU/Kg, once per week.

114. The method of claim 93 wherein the treatment period includes a titration period and the recombinant erythropoietin is administered at an initial dose of about 50 to about 100 IU/kg per week during the titration period and is adjusted by about 5 to about 25 IU/Kg/week to obtain a hemoglobin count of about 10 to about 12 g/dl.

115. The method of claim 93 wherein the treatment period further includes a maintenance period, and the recombinant erythropoietin is administered at a dose of about 40-60 IU/kg per week during the maintenance period.

116. A method of treating a patient comprising administering to the patient having a need thereof, a recombinant erythropoeti, wherein the recombinant erythropoetin provides a benefit selected from the group consisting of:

a. a serum concentration as measured by serum RIA testing that is 10% or more based on blood concentration over a clearance time compared to that of Epoetin Alfa or Beta;

b. a measurable response in hemoglobin or red blood cell count within 2 weeks or less;

c. a potency of 150% that of Epoetin Alfa or Beta as measured by an erythropoiesis response in humans per IU unit administered;

d. a reduction or elimination of body pain;

e. effectiveness in patients who are known or suspected non-responders to Epoetins Epoetin Alfa or Epoetin Beta;

f. effectiveness in increasing hemoglobin or red blood cell count in treating an anemia associated with chemotherapy or radiation therapy;

g. effectiveness in enhancement of mood or sense of well being;

h. reduced pain at the site of injection;

i. effectiveness in treating anemia of dialysis with an administration frequency of injection per week;

j. effectiveness in improving AST (GOT) and/or ALT (GPT) or other measurements of liver and/or heart condition;

k. effectiveness in treating anemia associated with heart disease or vascular impairment patient, without a measurable risk of myocardial infarction or thrombotic episode;

l. effectiveness in treating a liver impaired patient wherein said liver impairment is due to hepatitis, cirrhosis, auto immune disease, a chemical, or pathological liver dysfunction;

m. effectiveness in treating an anemia of chronic disease without a significant risk of an adverse reaction;

n. effectiveness in stimulation of red blood cell production, without increasing a systolic blood pressure measurement by more than 10 mm of Hg;

o. effectiveness in systolic enhancement of appetite, or the reduction of aversion to food/nourishment intake;

p. a longer duration of serum concentration as measured by RIA serum concentration levels than epoetin Alfa or Beta; and

q. not eliciting a detectable antigenic response in human over a course of 4-16 weeks of treatment , wherein said antigenic response is a measurable level of anit- rHU EPO IgG antibodies.

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